



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 112

[Docket No. FDA-2011-N-0921]

RIN 0910-AG35

Notice of Intent to Prepare an Environmental Impact Statement for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of Intent.

SUMMARY: Under the National Environmental Policy Act of 1969 (NEPA), as implemented by the Council on Environmental Quality (CEQ) regulations, the Food and Drug Administration (FDA) announces its intent to prepare an Environmental Impact Statement (EIS) to evaluate the potential environmental effects of the proposed rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. By this notice, FDA is announcing the beginning of the scoping process to solicit public comments and identify issues to be analyzed in an EIS. Information on the proposed rule may be accessed using the docket number found in brackets in the heading of this document.

DATES: This notice initiates the public scoping process for the EIS which will close on November 15, 2013. The Agency will consider comments in response to this notice to determine the need for any public scoping meetings prior to the preparation of the Draft EIS. In order to be considered during the preparation of the Draft EIS, all comments must be received prior to the close of the public scoping period. All relevant and substantive comments submitted to Docket

No. FDA-2011-N-0921 in response to the proposed rule will be considered as part of the scoping process. FDA will provide additional opportunities for public participation upon publication of the Draft EIS.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2011-N-0921 and/or Regulatory Information Number (RIN) 0910-AG35, by any of the following methods.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2011-N-0921 and RIN 0910-AG35 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Annette McCarthy, Center for Food Safety and Applied Nutrition (HFS-205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200.

SUPPLEMENTARY INFORMATION: To minimize the risk of serious adverse health consequences or death from consumption of contaminated produce, FDA has published the proposed rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption ("the produce safety rule" or "the proposed rule") to establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption (78 FR 3504, January 16, 2013). FDA has proposed these standards as part of our implementation of the FDA Food Safety Modernization Act (FSMA). These standards would not apply to produce that is rarely consumed raw, produce for personal or on-farm consumption, or produce that is not a raw agricultural commodity. In addition, produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance would be eligible for exemption from the requirements of this rule. The proposed rule would set forth procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards. We expect that the proposed rule, if finalized as proposed, would reduce foodborne illness associated with the consumption of contaminated produce.

For the proposed rule, the Agency relied on a categorical exclusion from the need to prepare an Environmental Assessment or EIS under 21 CFR 25.30(j). Based on currently

available information, including comments received, and upon further analysis, FDA has determined that the proposed action may significantly affect the quality of the human environment (21 CFR 25.22(b)) and, therefore, an EIS is necessary for the final rule. For example, switching from surface to ground water was originally considered a cost- and time-prohibitive option that was unlikely to occur to any significant extent given that monitoring data available prior to the publication of the proposed rule showed that Escherichia. coli exceedance of the proposed standard occurred during 5 percent of the monitoring period with 55 percent of the incidents being no more than 2 days, as discussed in the categorical exclusion memo (see Ref. 266 of the proposed rule). Public comment, subsequent to the publication of the proposed rule, has indicated that in some regions current irrigation practices use water that is unlikely to meet the proposed microbial standards for much, if not all of the growing season. Consequently, if such standards are finalized, ground water is likely to be explored as a more viable alternative water source for irrigation in these regions than previous information had indicated. Given recently highlighted concerns of ground water depletion (Ref. 1), FDA has determined that the use of ground water for irrigation, in response to a microbial standard, may significantly affect the quality of the human environment. Similarly, comments received caused FDA to reevaluate the proposed requirements for biological soil amendments of animal origin, which propose an increasingly stringent set of application restrictions based on the likelihood of the soil amendment harboring pathogens. These proposed requirements, if finalized, are expected to result in changes in current use of treated and untreated biological soil amendments of animal origin or potentially greater use of synthetic fertilizers. Changes in the type or handling of soil amendments may significantly affect the quality of the human environment.

The purpose of the public scoping process for the EIS is to determine relevant issues that will influence the scope of the environmental analysis, including potential alternatives, and the extent to which those issues and impacts will be analyzed in the EIS. The EIS will be prepared in accordance with section 102(2)(C) of NEPA (Public Law 91-190), FDA's NEPA implementing regulations (21 CFR part 25), and the CEQ regulations for implementing NEPA (40 CFR parts 1500-1508). Federal, State, and local Agencies, along with tribes and other stakeholders that may be interested in or affected by the produce safety rule are invited to participate in the scoping process. Some Federal Agencies may request or be requested by the FDA to participate in the development of the environmental analysis as a cooperating agency. FDA has previously sought comment on potential environmental effects as part of the public comment period for the proposed rule, including specific questions regarding agricultural water, biological soil amendments of animal origin, and wildlife (78 FR 3504 at 3616, 3619-3620). FDA believes that these questions are still relevant to the environmental analysis and will consider comments received. FDA encourages additional comments, as part of this scoping process, on what specific issues, alternatives, mitigation measures, or other information FDA should include for further analysis in the EIS for the produce safety rule.

References

The following reference has been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the Federal Register.)

1. U. S. Geological Survey. 2013. Groundwater Depletion in the United States (1900-2008). Scientific Investigation Report 2013-5079. Available at:
<http://pubs.usgs.gov/sir/2013/5079/SIR2013-5079.pdf>. Accessed July 30, 2013.

Dated: August 13, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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